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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PONNALURI, PADMASHRI	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,014	FANG, FANG	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *5-7, 9 and 10-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of group I, claims 1-4, 8-9; and species election of amino acid sequence of ICAM as 'PDGQSTAKTFLTVY', and the possible amino acids at each position, in the reply filed on 4/19/04 is acknowledged.

2. Claims10-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/2/03.

3. Claims 1-4 and 8 (in-part) (drawn to anti-sense peptides) withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/19/04.

4. Claim 9 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species election (NOTE applicants have elected 'ICAM-1' as the target protein, not immunoglobulin molecule), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/24/03.

5. Claims 1-4 and 8 (in-part) are currently being examined in this application.

Priority

6. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an

application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Information Disclosure Statement

7. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

8. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 1-4, 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites 'complement substantially the entire length of said target protein', which

is indefinite because the term "substantially the entire length of said target protein" is a relative term, which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicants are requested to amend the claim.

Claim 1 is vague and indefinite by reciting 'complementary peptides', the specification has no clear definition of the complementary peptides. However, the specification discloses that the complementary peptides can be based on the hydropathy of the amino acids or the antisense nucleic acid sequence. The complementary peptide sequence would differ based on the hydropathy or the antisense nucleic acid sequence. Thus the resulting complementary peptides have a different structure and function. Applicants are requested to amend the claim to include the definition of the complementary peptides in context of the currently elected invention.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-4, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,723,826 (DOWER et al) and US Patent 5,077,195 (BLALOCK et al).

The instant claim briefly recites a method of screening for peptide ligands of a target

protein, comprising the steps of: providing a collection of recombinant nucleic acids encoding complementary peptides of said target proteins, expressing said peptides from said recombinant nucleic acids; bringing said target protein into contact with said peptides expressed from said recombinant nucleic acids; and selecting one or more peptides expressed from said recombinant nucleic acids which bind to said target protein.

Dower et a l teach peptides which bind to selected receptor molecules are identified by screening libraries which encode a random or controlled collection of amino acids (refers to instant claimed method) (i.e., see the abstract). The reference teaches that the peptides encoded by the libraries are expressed as fusion proteins of bacteriophage coat proteins, and bacteriophage particles (refers tot eh genetic packages of the instant claims) are then screened against the receptor of interest (refers to the target protein of the instant claims) (i.e., see abstract). The reference teaches that the method comprises constructing a bacteriophage expression vector, which comprises an oligonucleotide library (refers to the collection of recombinant nucleic acids encoding the complementary peptides) of at least 10^6 members, which encode the peptides (i.e., see column 1, lines 61-64). The reference teaches that the receptor of interest may include cellular adhesion molecule (refers to the target protein ICAM-1 of the instant claim) (i.e., see column 3, lines 59).

The claimed invention differs from the prior art teachings by reciting complementary peptides. Dower et al teach peptides which bind to selected receptor molecules (i.e., ICAM), and bacteriophage expression vectors displaying the peptides. The reference does not teach that the peptides are complementary peptides. However, Blalock et al teach polypeptides complementary to peptides or proteins. The reference teaches methods for determining the amino acid sequence

of a polypeptide complementary to at least a portion of an original peptide or protein. The reference teaches that the complementary peptide whose amino acid sequence thus determined may by obtained by diverse means such as, inserting the DNA sequence into a plasmid to form a recombinant DNA plasmid vector (refers to the recombinant nucleic acid encoding complementary proteins of the instant claims) and transforming a unicellular organism biosynthesizing said complementary polypeptide (i.e., see the abstract). And the reference further teaches that the particular nucleic acid sequences may be circumvented, by utilizing the relationship of amino acids having complementary hydropathies for substitutions as generally dictated by base-pairing nucleotide complementarity (refers to instantly elelcted 'selection of amino acid based on hydropathy') (i.e., see the abstract).

Thus, it would have been obvious to one skilled in the art at the time the invention was made to use the nucleic acid sequences encoding the complementary peptides in the method of screening libraries taught by Dower et al, because Blalock et al teach that the advantages of the complementary proteins in therapy. A person skilled in the art would have been motivated to make complementary proteins using the recombinant methods taught by Dower et al, such that the vastly diverse peptides can be used in therapy and diagnostics.

13. Claims 1-4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 365837 B1 (Springer et al) and US Patent 5,077,195 (Blalock et al).

The instant claim briefly recites a method of screening for peptide ligands of a target protein, comprising the steps of: providing a collection of recombinant nucleic acids encoding complementary peptides of said target proteins, expressing said peptides from said recombinant nucleic acids; bringing said target protein into contact with said peptides expressed from said

recombinant nucleic acids; and selecting one or more peptides expressed from said recombinant nucleic acids which bind to said target protein.

Springer et al teach soluble, functional derivatives of intracellular adhesion molecule such as ICAM-1 (refers to instant claim target protein) (i.e., see page 3). The reference teaches vector library of cDNA inserts derived form ICAM-1 expressing cells (i.e., see page 10). The reference teaches identifying sequences that contain amino acids, which are encoded by similar oligonucleotides or oligonucleotides which have a nucleotide sequences that is complementary to oligonucleotide sequence or set of sequences that is capable of encoding the peptide fragment. And the suitable onligonucleotide or set of oligonucleotides which is capable of encoding a fragment of ICAM-1 gene is synthesized (i.e., see page 11). The reference teaches cloning ICAM-1 gene into expression vectors. The library is then screened for members capable of expressing a protein which binds to anti-ICAM 1 antibody, and which has a nucleotide sequence that is capable of encoding polypeptides that have same amino acid sequences as ICAM-1 or fragments of ICAM-1 (refers to the instant claim method). The reference teaches that pool of DNA which encode ICAM-1 is cloned into expression vector in order to produce a genomic library of expression vectors (i.e., see page 31), and the phage (refers to bacteriophage) DNA from positive clones.

The claimed invention differs from the prior art teachings by reciting complementary peptides. Springer et al teach recombinant nucleic acids encoding ICAM-1 and libraries. The reference does not teach that the recombinant nucleic acids encode complementary peptides. However, Blalock et al teach polypeptides complementary to peptides or proteins. The reference teaches methods for determining the amino acid sequence of a polypeptide complementary to at

least a portion of an original peptide or protein. The reference teaches that the complementary peptide whose amino acid sequence thus determined may by obtained by diverse means such as, inserting the DNA sequence into a plasmid to form a recombinant DNA plasmid vector (refers to the recombinant nucleic acid encoding complementary proteins of the instant claims) and transforming a unicellular organism biosynthesizing said complementary polypeptide (i.e., see the abstract). And the reference further teaches that the particular nucleic acid sequences may be circumvented, by utilizing the relationship of amino acids having complementary hydropathies for substitutions as generally dictated by base-pairing nucleotide complementarity (refers to instantly elelcted 'selection of amino acid based on hydropathy') (i.e., see the abstract).

Thus, it would have been obvious to one skilled in the art at the time the invention was made to use the nucleic acid sequences encoding the complementary peptides in the method of screening phage ICAM-1 libraries taught by Springer et al, because Blalock et al teach that the advantages of the complementary proteins in therapy. A person skilled in the art would have been motivated to make complementary proteins using the recombinant methods taught by Springer et al, such that the vastly diverse peptides can be used in therapy and diagnostics.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

PADMASHRI PONNALURI
PRIMARY EXAMINER

10 July 2004